

REMARKS

The Office Action of November 3, 2004, has been received and reviewed. Claims 1-20 are pending in the application of which claims 1-10 and 16-20 have been withdrawn from consideration as being directed to a non-elected invention. Claims 11-15 stand rejected. The applicant would like to thank the Examiner for the courtesy extended in the interview of March 28, 2005. Claims 11 and 15 have been amended as set forth herein. All amendments are made without prejudice or disclaimer. Reconsideration is requested.

Substance of the Interview

The Examiner provided an interview summary to the applicant's representatives for the interview with the Examiner on March 28, 2005, and checked a box indicating that it is not necessary for the applicant to provide a separate record of the substance of the interview.

The interview summary provided by the Examiner indicated that JaNa Hines, Johan Renes, Allen Turner, and Paulus Steverink attended the interview.

The interview summary further indicated that amendment suggestions for claim 11 were discussed and are presented in the instant amendment.

The interview summary accurately describes the interview and, thus, the above statement is made in accordance with M.P.E.P. § 713.04.

Rejection under 35 U.S.C. § 112

Written Description

Claims 11-15 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the written description requirement. Applicant respectfully traverses the rejections as hereinafter set forth.

It was thought that the instant specification and claims encompass unidentified nucleic acid molecules and that the sequences may be any nucleic acid molecule of a *Streptococcus* origin. (See, Office Action, page 3). Although applicant does not agree that any of the claims lack compliance with the written description requirement, to expedite prosecution and as discussed at the interview, claim 11 has been amended to recite an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin comprising: a nucleotide sequence capable of

hybridizing to the full length of a nucleotide sequence selected from the group of nucleotide sequences consisting of SEQ ID NOS: 15, 16, 17, 24, 31, 33, 34, 37, 41 and 43; wherein the hybridizing occurs at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2.

Support for the hybridization conditions of amended claim 11 is found, *inter alia*, at paragraph [0066] of the as-filed specification. Support for the sequence identifiers of amended claim 11 is found, *inter alia*, in the as-filed specification as follows: SEQ ID NO: 15, paragraphs [0046], [0047] and Table 2; SEQ ID NO: 16, Table 2; SEQ ID NO: 17, paragraph [0056] and Table 2; SEQ ID NO: 24, paragraph [0050] and Table 2; SEQ ID NO: 31, paragraphs [0050], [0056], [0058] and Table 4; SEQ ID NO: 33, paragraphs [0050], [0056] and Table 4; SEQ ID NO: 34, paragraphs [0050], [0053], [0054], [0056] and Table 4; SEQ ID NO: 37, paragraphs [0050], [0053], [0062], [0079] and Table 4; SEQ ID NO: 41, Table 4; and SEQ ID NO: 43, paragraphs [0050], [0053], [0056], [0084] and Table 4. Support for the sequence identifiers is also found in the Sequence Listing of the as-filed specification.

Thus, one of ordinary skill in the art would conclude that the applicant was in possession of amended claim 11 at the time the application was filed.

Claims 12-15 should comply with the written description requirement as depending from amended claim 11.

With further regard to claim 15, the Office Action asserted that the written description fails to set forth a vaccine comprising a nucleic acid molecule. (*See, Office Action* at page 7). Although applicant does not agree with the rejection, to expedite prosecution, claim 15 has been amended to be directed towards a "composition" comprising the isolated or recombinant nucleic acid molecule of claim 11 rather than a "vaccine."

Reconsideration and withdrawal of the written description rejections of claims 11-15 are requested.

Enablement

Claims 11-15 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the enablement requirement. Applicant respectfully traverses the rejections as set forth herein.

Specifically, it was thought that the specification fails to teach how to determine which nucleic acids comprise the nucleic acid molecule. (See, Office Action at page 9). It was further thought that the specification fails to include a description of a structure or relevant identifying characteristic of a representative number of nucleic acids. (See, *Id.*)

As discussed at the interview, amended claim 11 is directed towards an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin comprising: a nucleotide sequence capable of hybridizing to the full length of a nucleotide sequence selected from the group of nucleotide sequences consisting of SEQ ID NOS: 15, 16, 17, 24, 31, 33, 34, 37, 41 and 43; wherein the hybridizing occurs at 65°C in a buffer having 0.5 M sodium phosphate, 1 mM EDTA, and 7% sodium dodecyl sulphate at a pH of 7.2.

Paragraph [0066] of the as-filed specification describes how to make and use a nucleotide sequence that is capable of hybridizing to a nucleotide sequence of an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin. Further, paragraph [0079] of the as-filed specification describes a working example of an isolated or recombinant nucleic acid molecule of a *Streptococcus* origin comprising a nucleotide sequence capable of hybridizing to the full length of a nucleotide sequence selected from the group of nucleotide sequences consisting of SEQ ID NOS: 15, 16, 17, 24, 31, 33, 34, 37, 41 and 43. Thus, one of ordinary skill in the art would be able to make and use the isolated or recombinant nucleic acid molecule of amended claim 11 without undue experimentation.

Claims 12-15 are enabled, at the very least, as depending from amended claim 11.

With further regard to claim 15, it was thought that the instant specification fails to provide any experiments that show that such vaccines would be effective in protecting a human or other animal against a *Streptococcal* or any other bacterial infection. Although applicant does not agree with the enablement rejection of claim 15, it has been amended to be directed towards a "composition" rather than a "vaccine."

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Reconsideration and withdrawal of the enablement rejections of claims 11-15 are requested.

CONCLUSION

In view of the foregoing amendments and remarks, it is submitted that claims 11-15 are in condition for allowance and a notice thereof is solicited. Should questions remain after consideration of the foregoing, the Office is kindly requested to contact the applicant's attorney at the address or telephone number given herein.

Respectfully submitted,



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